SYNTHES® Spine

MAY 2 4 2013

6 510(k) Summary : K122639

510(k) Summary –SynCage Evolution Spacer	
Name of Firm:	DePuy Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Hemal Mehta Regulatory Affairs Specialist Telephone: 610-719-5424 Facsimile: 610-719-5102 Email: mehta.hemal@synthes.com
Date Prepared:	May 22, 2013
Trade Name(s):	Synthes SynCage Evolution Spacer
Classification:	21 CFR 888.3080 – Intervertebral Body Fusion Device Class II (special controls) Orthopaedic and Rehabilitation Devices Panel (87) Product Code MAX (Intervertebral Fusion Device with Bone Graft, Lumbar)
Predicates:	Synthes OPAL Spacer (K072791) LDR Spine ROI-A (K090507) Biomet Enclave (K081636) SeaSpine Redondo (K082310) DePuy Spine Cougar (K081917 & K113348)
Device Description(s):	The Synthes SynCage Evolution spacer is a radiolucent device for use in interbody fusion. It is to be used in conjunction with supplemental fixation to provide structural stability in skeletaly mature individuals. The Synthes SynCage Evolution spacer is fabricated from Invibio® PEEK-OPTIMA® LT-1 (ASTM F2026-10) with four anterior and one posterior tantalum (ASTM F560-08) radiopaque markers. The markers allow intra-operative radiographic assessment of the position of the implant. Implantation is through an anterior or anterolateral approach. The Synthes SynCage Evolution spacer is provided sterile. The Synthes SynCage Evolution spacer is available in three footprints (Small: 32x25mm; Medium, 36x28mm; Large, 40x31mm), four lordotic angles (6°, 10°, 14°, 18°), and a range of heights (9-19mm) to suit individual pathology and anatomical conditions. Pyramidal teeth that assist in stabilization of the construct are located on the inferior and superior surfaces of the spacers. The open architecture of the device allows it to be packed with autogenous bone graft material (*i.e.*, autograft).
Intended Use/ Indications for	The SynCage Evolution spacer is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2

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Use:	to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the SynCage Evolution spacer should be packed with autogenous bone graft (i.e. autograft). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.
Comparison of the device to predicate device(s):	Synthes SynCage Evolution Spacer is substantially equivalent to the predicates in design, function, performance, material, and intended use.
Performance Date (Non-Clinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* Synthes conducted the following bench testing (as recommended within FDA Guidances and in accordance with ASTM F2077-11 and ASTM F2267-04): Static Axial Compression; Dynamic Axial Compression; Static Compression Shear; Expulsion; and Subsidence. The conclusions drawn from testing and an engineering rationale demonstrate that the Synthes SynCage Evolution Spacer is substantially equivalent in performance to predicate devices. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Synthes (USA) Products LLC
% Mr. Hemal Mehta
Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Letter dated: May 24, 2013

Re: K122639
Trade/Device Name: Synthes SynCage Evolution Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 30, 2013
Received: May 1, 2013

Dear Mr. Mehta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®
Spine

6 Indications for Use Statement

510(k) Number(s): K122639
(if known)

Device Name: Synthes SynCage Evolution Spacer

The SynCage Evolution spacer is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the SynCage Evolution spacer should be packed with autogenous bone graft (i.e. autograft). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Prescription Use X (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices